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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/800,052

03/12/2004

William K. Keener

B-221

9113

7590

10/30/2006

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/800,052

Applicant(s)

KEENER, WILLIAM K.

Examiner

Daniel M. Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 2-5, 7-10 and 12-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |                                                                                        |                                                                               |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)                       |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                                  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application             |
| Paper No(s)/Mail Date <u>3/12/04</u> .                                                 | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL.

### **DETAILED ACTION**

This is the First Office Action on the Merits of the application filed 12 March 2004.

Claims 1-23, as originally filed, are pending.

#### ***Election/Restrictions***

Applicant's election without traverse of Group I (claims 1-10 and 13-19) and the vector pWKK-500 in the reply filed on 20 September 2006 is acknowledged. It is noted that in the 20 September response, Applicant refers to pWKK-500 as an elected species. However, the distinct vectors are actually viewed as distinct inventions, not species of a generic invention, in view of the fact that the application does not disclose a vector that is generic to all of the vectors recited in the claims. As noted in the restriction requirement, the oligonucleotides of claims 11 and 12 appear to be comprised within some of the claimed plasmids and, therefore, claims 11 and 12 will be viewed as linking claims. Should the oligonucleotides be found allowable, any vectors limited to comprising the oligonucleotide sequence will be rejoined. As it appears that it is the oligonucleotide of claim 11 that is comprised within the elected vector pWKK-500, claim 11 is examined and claim 12 is withdrawn from consideration in this Office Action:

Claims 2-5, 7-10 and 12-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the 20 September reply.

Claims 1, 6 and 11 are presently under consideration.

#### ***Specification***

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Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains more than 150 words.

Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities: Paragraph 0042, line 3 contains misformatted text (i.e., the box between 37 and C).

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The claims are drawn to the plasmid pWKK-500. As such, this application discloses nucleic acid molecule that is encompassed by the definitions for biological material set forth in 37 C.F.R. §1.801. Because it is apparent that this biological material is essential for practicing the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be known and readily available to the public as detailed in 37 C.F.R. §§1.801 through 1.809.

It is unclear that the plasmid of the claims will be readily available to the public or that the written instructions are sufficient to reproducibly construct this biological material from starting materials known and readily available to the public. The plasmid is most particularly described in ¶0044 of the specification, which provides a list of functional elements and states, "The nucleotide sequence of this sequence of functional elements is set forth in SEQ ID NO: 2." It is unclear, however, the entirety of the plasmid pWKK-500 is disclosed as SEQ ID NO: 2 or whether pWKK-500 comprises the recited functional elements as set forth in SEQ ID NO: 2 and additional elements. Therefore, it is unclear that the specification would enable the skilled artisan to make what is claimed (i.e., the plasmid identified as pWKK-500).

This rejection can be overcome by the submission of a biological deposit of the claimed plasmid pWKK-500. In order for a deposit to meet all criteria set forth in 37 C.F.R. §§1.801-1.809, the Applicant or Assignee must provide assurance of compliance with provisions of 37 C.F.R. §§1.801-1.809 in the form of a declaration or Applicant's representative must provide a statement. The content of such a declaration or statement is suggested by the enclosed attachment. Because such deposit will not have been made prior to the effective filing date of the instant application, Applicant is required to submit a verified statement from a person in a

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position to corroborated the statement that the biological material which has been deposited is the biological material specifically identified in the application as filed (37 C.F.R. §1.804. Such a statement need not be verified if the person is an agent or attorney registered to practice before the Office. Applicant is also reminded that the specification must contain reference to the deposit, including deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Keener (2001) WO 01/60393.

The claim is directed to an oligonucleotide encoding an HIV protease-cleavable peptide linker, wherein the oligonucleotide is “represented by SEQ ID NO: 36”. As the disclosure provides no limiting definition of the metes and bounds of representation by a given SEQ ID NO, the claim can be reasonably be construed as encompassing any oligonucleotide that encodes the same HIV protease-cleavable peptide linker as encoded by SEQ ID NO: 36. In other words, it is reasonable to consider SEQ ID NO: 36 as representative of any oligonucleotide having the same function (i.e., encoding an HIV protease-cleavable peptide linker). Keener et al. discloses an oligonucleotide as SEQ ID NO: 5 which encodes a polypeptide that is 100% identical to the

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polypeptide encoded by the instant SEQ ID NO: 36<sup>1</sup>. Therefore, the teachings of Keener et al. anticipates the claimed oligonucleotide.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Daniel M. Sullivan, Ph.D.

Primary Examiner

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<sup>1</sup> The encoded linker is set forth in the instant application as SEQ ID NO: 8 and is encoded by SEQ ID NO: 36 beginning at nucleotide 10 through nucleotide 29.



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SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

ATTACHMENT

A declaration by applicant or assignee, or a statement by applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection or rejection based on a lack of availability of biological material. Such a declaration:

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address. (See 37 C.F.R. § 1.803).
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of the patent. (See 37 C.F.R. § 1.808(a)(2)).
5. States that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122. (See 37 C.F.R. § 1.808(a)(1)).
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit or for the enforceable life of the patent, whichever period is longer. See 37 C.F.R. § 1.806).
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository, and the complete taxonomic description.